

### **REMARKS/ARGUMENTS**

The Office Action of August 29, 2003 has been carefully reviewed and these remarks are responsive thereto. Reconsideration and allowance of the instant application are respectfully requested.

Claims 1-2, 4-7 and 18-23 are pending. By this amendment and pursuant to an earlier restriction requirement, Group 1 was elected and claims that fall within this group are claims 1-7 and new claims 18-23. Based on the election, claims 8-17 are withdrawn. By this Amendment, claim 3 is cancelled.

Claims 1-2 were rejected under 35 U.S.C. § 102(b) as being anticipated by Rise (U.S. Pat. No. 5,643,203), Otto (U.S. Pat. No. 5,769,823), and Elsberry et al. (U.S. Pat. No. 5,711,316). Claims 1-2 were also rejected under 35 U.S.C. § 102(e) as being anticipated by Elsberry et al. (U.S. Pat. No. 5,832,932) ("the '932 patent"). Claims 3-4 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Rise, Otto and Elsberry in view of Seckel (U.S. Pat. No. 5,584,885). Claims 5-6 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Rise, Otto and Elsberry in view of Hadden (U.S. Pat. No. 5,632,983) and Masters (U.S. Application No. 2003/0007991). Claim 7 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Rise, Otto and Elsberry in view of Medenica et al. (U.S. Pat. No. 5,738,129). Claim 7 was also rejected under 35 U.S.C. § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention.

In response, the Applicant has amended claim 1 to include a limitation previous recited in claim 3. The Applicant has modified claim 7 to clarify the subject matter claimed. The applicant has also added dependent claims 18-23. The Applicant respectfully traverses the Examiner's rejection of claims 1-2 and 4-7 and submits the following remarks.

### **Newly Added Claims**

Claims 18-23 have been added and are believed to be patentable over all prior art of record. Thus, claims 18-23 are believed to be in allowable condition. Favorable consideration of new claims 18-23 is earnestly requested.

**Rejection Under 35 U.S.C. § 112**

Dependent claim 7 was rejected under 35 U.S.C. § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. In response, the Applicant has amended claim 7 to clarify the recited subject matter. In addition, the Applicant has added claims 18-19 to help clarify the subject matter of claim 7. Support for the modified claim is found in the specification at paragraph 10, and paragraph 25, thus no new matter has been added. The Applicant respectfully submits that as currently provided, claims 7 does distinctly point out and claim the subject matter regarded as the invention. Therefore, Applicant respectfully requests withdrawal of this ground for rejection.

**Rejection Under 35 U.S.C. § 102**

Claims 1 and 2 were rejected under 35 U.S.C. § 102(a) as being anticipated by Rise, Otto and Elsberry et al. Claims 1 and 2 were also rejected under 35 U.S.C. § 102(e) as being anticipated by the '932 patent. While not admitting the above references are prior art, the Applicant has amended claim 1. Claim 1 now recites "the medicament composition including living cells" and this limitation is not found in the above references. As Rise, Otto, Elsberry et al., or the '932 patent do not have every limitation of claim 1, Rise, Otto, Elsberry et al. and the '932 patent cannot anticipate claim 1 (or claims dependent therefrom). Thus, Applicant respectfully requests withdrawal of this ground for rejection.

**Rejection Under 35 U.S.C. § 103(a) – Rise, Otto and Elsberry in view of Hadden and Masters**

Claims 5 and 6 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Rise, Otto and Elsberry in view of Hadden and Masters. The Applicants respectfully submit that Masters cannot be fairly considered prior art for the present invention. While not addressing the merits of the priority claim, Masters claims priority to U.S. Provisional Application Ser. No. 60/222,762, filed on Aug. 3, 2000. (Masters, pg. 1, col. 1., ¶ 1). The present invention, however, claims priority to U.S. Application Ser. No. 09/303,033, filed April 30, 1999. As the priority date of the present invention precedes the priority date of Masters, the Applicant

respectfully submit that Masters cannot be fairly considered prior art for the present invention. Therefore, Masters, or the combination of Hadden and Masters cannot make claims 5 and 6 unpatentable under 35 U.S.C. § 103(a). Applicant respectfully requests withdrawal of this ground for rejection.

**Rejection Under 35 U.S.C. § 103(a) – Rise, Otto and Elsberry in view of Seckel, Hadden and Medenica et al.**

Claims 3-4 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Rise, Otto and Elsberry et al. in view of Seckel. Claims 5-6 were rejected under 35 U.S.C. § 103(a) over Rise, Otto and Elsberry et al. in view of Hadden and Masters. Claim 7 was rejected under 35 U.S.C. § 103(a) over Rise, Otto and Elsberry et al. in view of Medenica et al. As previously discussed, Rise, Otto and Elsberry et al. do not teach claim 1 of the present invention. As noted above, Masters cannot fairly be considered prior art for the present invention. The Applicants respectfully submit that Rise, Otto and Elsberry et al. in combination with Seckel, Hadden and/or Medecina et al., fails to disclose, teach or suggest claim 1 of the present invention.

Seckel discloses a regeneration chamber for controlling the growth of biological nerves. (Seckel, Col. 3, Ln. 55-58). In Seckel, the regeneration chamber is inserted in the body and the chamber encloses the area of nerve tissue where growth is desired. (Seckel, Col. 5, Ln. 1-3). Seckel discloses the use of an inlet port on the chamber for providing agents to promote the growth of the nerve tissue and also discloses the use of an outlet port to remove fluid and particles from the chamber. (Seckel, Col. 5, Ln. 30-37). Seckel does disclose using living cells such as embryonic tissue cells. (Seckel, Col. 7, Ln. 25-27). Seckel, however, does not disclose an “implantable infusion device for delivering a medicament composition to a target site in the living body through a catheter.” Rather, Seckel teaches to use a chamber having both an inlet and outlet port and teaches away from using an inlet port without an outlet port. (Seckel, Col. 6, Ln. 3-14).

Hadden discloses a method of treating cellular immune deficiency, including the step of administering an agent containing an effective amount of a peptide and a cytokine preparation. (Hadden, Col. 4, Ln. 3-9). The agent can be administered through implantable infusion pump.

(Hadden, Col. 8, Ln. 16-25). Hadden, however, does not disclose the addition of a “medicament composition including living cells” because Hadden is directed towards treating cells already within the living body.

Medecina et al. discloses a method of treating cancer. Medecina et al. discloses taking cancer cells from a patient and forming a cell suspension. (Medecina et al., Col. 4, Ln. 6-9). The cell suspension is then purified of non-cancer cell components and used to create drug samples. (Medecina et al., Col 4, Ln. 9-14). The drug samples are then treated with various drugs to determine the resistance of the cancer cells to the various drugs. (Medecina et al., Col 4, Ln. 14-23). Thus, Medecina et al. does not suggest or teach providing a “medicament composition including living cell.” Rather, Medecina et al. teaches to add drugs that are adapted to kill cancer cells and thus teaches away from a “medicament composition including living cells.”

The Applicant respectfully submits that nothing in the above references suggests the combination of the various limitations to reach claim 1 of the present invention. Indeed, Seckel and Medecina et al. teach away from the present invention. In addition, the Applicant respectfully asserts that nothing in the above references suggests that the combination would likely be successful. *See* MPEP 706.02(j) (“To establish a *prima facie* case of obviousness, three basis criterion must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success.”). Specifically, the above references fail to disclose, teach or suggest an “implantable infusion device for delivering a medicament composition to a target site in the living body through a catheter” with “the medicament composition including living cells.”

Therefore, the Applicant submits that Rise, Otto and Elsberry et al. in combination with Seckel, Hadden and/or Medecina et al. fail to disclose, teach or suggest independent claim 1 of the present invention, rendering claim 1 nonobvious and further rendering dependent claims 2, 4-7, and 18-23 nonobvious for the additional limitations recited therein. Thus, Applicants respectfully request withdrawal of these grounds for rejection.

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Amendment dated November 10, 2003  
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**CONCLUSION**

It is believed that no fee is required for this submission. If any fees are required or if an overpayment is made, the Commissioner is authorized to debit or credit our Deposit Account No. 19-0733, accordingly.

All rejections and objections having been addressed, Applicant respectfully submits that the instant application is in condition for allowance, and respectfully solicits prompt notification of the same.

Respectfully submitted,

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